NOV 1 5 2001

K013278

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 521 – 7643

Contact Person: Helen T. Torney

Date Prepared: September 27, 2001

Device Name

Proprietary name: Tina-quant Apolipoprotein A-1 ver.2

Common name: Apolipoprotein A-1

Classification name: Alpha-1- lipoprotein immunological test system

Device Description

Human apolipoprotein A-1 forms a precipitate with a specific antiserum which is determined turbidimetrically at 340 nm.

Intended use

In vitro diagnostic reagent system intended for use on COBAS INTEGRA system for the quantitative immunological determination of human apolipoprotein A-1 in serum and plasma.

Indications for Use

For the quantitative determination of apolipoprotein A-1 in serum and plasma. A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders and atherosclerosis.

510(k) Summary, Continued

Substantial Equivalence

The Tina-quant Apolipoprotein A-1 ver.2 is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the COBAS Integra Tina-quant Apolipoprotein A-1 (K990594).

Substantial equivalence - similarities

The following table compares the Tina-quant Apolipoprotein A-1 ver.2 Assay with the predicate device.

Feature	Tina-quant Apolipoprotein A-1 ver.2	Apolipoprotein A-1 (predicate)
Intended Use	In vitro diagnostic reagent system intended for use on COBAS INTEGRA system for the quantitative immunological determination of human apolipoprotein A-1 in serum and plasma.	In vitro diagnostic reagent system intended for use on COBAS Integra (analyzer model) for the quantitative immunological determination of human apolipoprotein A-1 in serum and plasma.
Indication for Use	For the quantitative determination of apolipoprotein A-1 in serum and plasma. A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders and atherosclerosis.	For the quantitative determination of apolipoprotein A-1 in serum and plasma. A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders and atherosclerosis.
Assay Protocol	Immunoturbidimetric	Immunoturbidimetric
Instrument	COBAS Integra Clinical Chemistry Analyzers	COBAS Integra Clinical Chemistry Analyzers
Traceability / Standardization	Standardized with regard to the WHO/IFCC reference material SP1-01.	Standardized with regard to the WHO/IFCC reference material SP1-01.
Sample Type	Serum and plasma	Serum and plasma

Feature	Tina-quant Apolipoprotein A-1 ver.2	Apolipoprotein A-1 (predicate)
Calibration Interval	After each lot	After each lot
Formulation	**R**: TRIS buffer, polyethylene glycol, detergent, preservative (liquid). **SR**: Anti-apolipoprotein A-1 antibody (sheep) specific for human Apo A-1, TRIS buffer, preservative (liquid).	**R**: Anti-apolipoprotein A-1 T antiserum (rabbit) specific for human Apo A-1, in phosphate buffer stabilized with 0.09% sodium azide in vial A (liquid).

Substantial equivalence – differences

The following table compares the Tina-quant Apolipoprotein B ver.2 Assay with the predicate device.

Feature	Tina-quant Apolipoprotein A-1 ver.2	Apolipoprotein A-1 (predicate)
Reagent Stability	On board: 4 weeks	On-board: 12 weeks
Calibrator	C.f.a.s. Lipids	Apolipoprotein T Standard
Controls	Precinorm L, Precipath L	Apolipoprotein T Control
Expected Values	Females:1.08-2.25 g/L Males: 1.04-2.02 g/L	Females: 1.10-2.05g/L Males: 1.10-1.80 g/L
Measuring Range	0.20 – 4.0 g/L (0.10 – 4.0 g/L with rerun)	0.37-4.0 g/L (0.12 – 5.6 g/L with rerun)

510(k) Summary, Continued

Substantial equivalence – performance characteristics

The performance characteristics of the Tina-quant Apolipoprotein A-1 ver.2 Assay and the predicate device are compared in the table below.

Feature	Tina-quant Apolipoprotein A-1 ver.2	Apolipoprotein A-1 (predicate)
Precision	**Within run CV** 1.0% @ 0.88 g/L 0.8% @ 1.64 g/L **Between Day CV** 2.4% @ 0.88 g/L 1.7% @ 1.64 g/L	**Within run CV** 1.5% @ 0.68 g/L 1.0% @ 2.7 g/L **Between Day CV** 1.2% @ 0.68g/L 0.78% @ 2.7 g/L
Method Comparison	Bablok/Passing: Tina-quant Apolipoprotein A-1 ver.2 (Y) / COBAS Integra Apolipoprotein A-1 (X). y = 0.87x + 0.25 g/L r = 0.940	Bablok/Passing: Apolipoprotein A-1 (Y)/ commercially available system (X). y = 1.19x- 0.2 g/L r = 0.993
Prozone Effect	>6 g/L	>5.8g/L
Analytical sensitivity (LDL)	0.058 g/L (5.8 mg/dL)	0.37 g/L (37mg/dL)

Premarket Notification, 510(k) for Tina-quant Apolipoprotein A-1 ver. 2 Test System on COBAS Integra Clinical Chemistry Analyzers, continued

Substantial equivalence – performance characteristics, cont.

The performance characteristics of the Tina-quant Apolipoprotein A-1 ver.2 Assay and the predicate device are compared in the table below.

Feature	Tina-quant Apolipoprotein A-1 ver.2	Apolipoprotein A-1
Limitations	• Icterus: No significant interference • Hemolysis: No significant interference • Lipemia: No significant interference up to an Intralipid level of 1000 mg/dL • Rheumatoid factors: No significant interference	• Icterus: No significant interference • Hemolysis: No significant interference • Lipemia: No significant interference • Rheumatoid factors: No significant interference

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Helen Torney
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Roche Diagnostics Corporation
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P.O. Box 50457
Indianapolis, IN 46250-0457

NOV 1 5 2001

Re: k013278
Trade/Device Name: Tina-quant Apolipoprotein A-1 ver.2
Regulation Number: 21 CFR 866.5580
Regulation Name: Alpha-1-lipoprotein immunological test system.
Regulatory Class: Class II
Product Code: DER
Dated: September 27, 2001
Received: October 1, 2001

Dear Ms. Torney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013278

Indications for Use Statement

NOV 1 5 2001

510(k) Number (if known): N/A

Device Name: Tina-quant Apolipoprotein A-1 ver.2

Indications For Use:

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For the quantitative determination of apolipoprotein A-1 in serum and plasma. A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders and atherosclerosis.

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013278